Introduction

I would like to first thank the Committee for calling this hearing today on generic prescription drugs. Our company has been creating and implementing programs to promote generic as an effective alternative to expensive brand name prescription drugs for years. Caremark is pleased that the Congress is interested in the health care improvement and cost savings opportunities that are represented by generics.

I am a physician and the Chief Clinical Officer for Caremark. At Caremark I am responsible for the physician oversight of the Caremark corporate clinical strategy, support of sales and account management, governmental and lobbyist activities, Medicare Part D, product development, disease management and technology initiatives including: e-prescribing and Internet activities. I am a board certified pediatrician with clinical experience in private, managed care and academic medicine.

Caremark appreciates the opportunity to offer testimony on generic prescription drugs. Generic drugs represent a cost effective alternative to expensive brand name prescription drugs. By making this cost effective alternative available to patients, patient adherence to therapy increases, clinical outcomes are improved and healthcare costs are reduced. We commend the Energy and Commerce Subcommittee on Health for considering this very important issue. Based on its many years of experience in managing the pharmacy benefits for tens of millions of Americans, Caremark is pleased to be able to offer its comments and recommendations.

I will touch on three major points in my testimony to you today. First, I will explain how Caremark and the pharmacy benefit management (PBM) industry generally promotes generic drug utilization. Second, I will discuss some of the challenges we face in trying to increase generic utilization, and the efforts Caremark has made to increase consumer and provider awareness of generic drugs. Third, I will identify some of the more significant federal policy barriers we see to increased utilization of generic drugs.

Caremark Rx Inc. and the Impact of Generic Prescription Drugs on Our Market

Caremark Rx, Inc. (Caremark or "the company") is a leading pharmacy benefit management (PBM) company, providing through its affiliates comprehensive drug benefit services to over 2,000 health plan sponsors and their plan participants throughout the U.S. Caremark's clients include employers, health plans, managed care organizations, insurance companies, unions, government agencies, including the Federal Employees Health Benefits Program (FEHBP), CalPERS, and other funded benefit plans. Caremark operates a national retail pharmacy network with over 59,000 participating pharmacies, seven mail-service pharmacies, the industry's only FDA-regulated repackaging plant, and 21 licensed specialty pharmacies for the delivery of specialty medications to individuals with chronic or genetic diseases and disorders. Caremark processes over 550 million prescriptions annually.

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The Promise of Generic Drugs

The Congressional Budget Office (CBO) estimated that in 2002 the selection of generic drugs enabled savings of almost $100 billion vs. the costs for the equivalent brand name prescriptions. In addition, as blockbuster brands are losing their patent protection, more generic drugs are being introduced to the market every year. Every generic drug introduction is an opportunity to increase generic drug utilization.

Promoting the use of generic drug alternatives is a key factor in helping to control total prescription drug costs in the U.S.. Prescription drug spending grew at an annual rate of 10.7 percent from 2002 to 2003, reaching 11 percent of total national health spending in 2003.[1] If generic drug alternatives are introduced into the market, current brand name drug prices decline. A recent report indicated that "prices decrease 30 percent during the first 6-12 months after a generic drug enters the market, during which time only a single manufacturer may produce the generic, after which the price may decrease by as much as 70 percent when other generic drug competitors enter the market". [2]

[1] Cynthia Smith et al. "Trends: Health Spending Slows in 2003". *Health Affairs*, Volume 24, Number 1. January/February 2005.

[2] Milne, Christopher-Paul and Catherine Cairns. "Generic Drug Regulation in the US Under the Hatch-Waxman Act". *Pharmaceutical Development Regulation 2003;* 1(1). Tufts Center for the Study of Drug Development, Tufts University.

In an environment where health care costs are on the rise, it is vital that the cost savings available from increase generic drug utilization be realized. This is particularly relevant as the first outpatient drug benefit in the Medicare program is implemented January 1, 2006. Policy makers and industry stakeholders will want to ensure that there is an appropriate balance between quality of care delivered and effective cost-containment strategies, such as generic drug utilization.

The FDA ensures that generic medications maintain the same high standards of safety, strength, quality, and effectiveness as brand name medications. Since generic drugs contain the same active ingredients in the same amounts as brand drugs, they're just as safe and just as effective. In fact, the two versions are equal in strength and perform the same way within the body. Through strict regulations and scrutiny, the FDA ensures these similarities. That means, beyond the name, generic drugs and brands are *therapeutically equivalent* and *bioequivalent*[3].

[3] **Therapeutically Equivalent:** Two drugs are considered therapeutically equivalent if they can be expected to produce the same clinical effect with the safety profile.
Bioequivalent: Acting on the body with the same strength and similar bioavailability as the same dosage of a sample of a given substance. Use of differing formulations of a drug or chemical compound. Two drugs are considered bioequivalent if they contain the same active pharmaceutical ingredient and if there is no significant difference in the rate, and extent to which, the products are absorbed in the human body under similar experimental conditions, when administered at the same dose. *See* Food, Drug and Cosmetic Act, 21 U.S.C. § 505(j)(8)(B).

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Based on FDA guidelines, the only differences between brand name and generic drugs are their **name, appearance** and **price**. By law, generic drugs must look different from their brand name counterpart: what is sold as a blue pill from the brand manufacturer might be sold as a white pill from the generic manufacturer. And, because generic drugs can have multiple competitors and don't carry the high costs of research and advertising, they can be sold at a much lower cost. Prescription generic medication essentially is the same as the brand name drug in everything but name. That is why generic drugs are such a great value for patients and health plans, patients can receive the same medication, just as safe and just as effective as the brand, for a much better price. In short, the promise of generic drugs is equal effectiveness *and* lower costs.

Based on Caremark's experience in managing drug benefit programs in a wide variety of settings, we can say unequivocally that one of the simplest and most effective ways to control drug costs while maintaining high quality care is to increase the use of generic, as compared to brand, medications by patients. For example, generic drugs introduced over the last three years alone reduced total drug costs for Caremark's health plan clients in 2003 by 3.1 percent**.** By increasing generic drug substitution, health plans typically realize a savings of 30-70 percent compared to use of the more expensive brand-name drugs Caremark's programs to increase generic utilization have two main areas of focus:

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- **Education- Empower and educate the physicians and patients about** the safety and effectiveness, as well as lower cost, of generic drugs through proactive, concurrent and retrospective programs.
- **Plan Design-** Structuring the plans designs to encourage the use of generic drugs.

In addition to patients and physicians, the dispensing pharmacist is also an important decision-maker with regards to generic drug dispensing. Caremark recognizes this and works with our network pharmacies in a variety of ways to maximize the potential value for our clients and their members from generic drugs. These include on-line communications at the point of sale that alert a pharmacist to potential generic drug dispensing opportunities, financial incentives for pharmacies to dispense generic drugs rather than more costly brand alternatives, and extensive analytic and reporting tools to further help pharmacies recognize and maximize generic dispensing opportunities.

Raising Awareness

Why doesn't everyone use generic drugs? There are many outside influences that work against the average consumer's choice to use generic drugs. The most obvious are:

- **Awareness:** Many patients are simply unaware that generic drugs are *just as safe* and *just as effective* as their brand name counterparts. They may also be unaware that a generic drug

exists for the prescription they are filling. And they may not know they can ask their doctor or pharmacist for the generic version.

- **Visibility:** Blockbuster brands have a strong marketing presence through direct-to-consumer advertising, while prescription generics do not.

- **Mistaken Identity:** People often associate the term ”generic” with lower quality (e.g., “Brand X” generic paper towels). In the case of generic drugs, ”generic” simply means a non-branded prescription medication.

- **Motivation:** If patients pay nearly the same co-pay for a brand name drug and a generic drug, then there’s little reason for them to choose the generic. Creating a pharmacy plan that clearly distinguishes the economic or financial benefits of using generic drugs will motivate patients to learn more about and use generic drugs.

- **Physician Focus:** It’s often easier to prescribe, pronounce and spell a brand name drug name (e.g., Dyazide) than a generic one (hydrochlorothiazide/triamterene). The priority for physicians is the clinical care of their patients; drug costs are secondary. Studies have found that approximately 23 percent of physicians could correctly identify the price of common prescription medications. While, physicians aren’t directly impacted by the actual cost of brand medications; they do, however, receive brand samples and substantial marketing and sales attention from brand name drug manufacturers.

- **Powerful Patents:** The patents for many brand name drugs are vigorously defended even after the protection period is over. Brand manufacturers often try to extend their patents and exclusivity periods to protect their product from competition by generic drugs. Sometimes brand manufacturers create new formulations or "me-too" variations to the original brand to divert attention from the generic drug.

These issues affect patients in their homes, at the physician's office, and at the pharmacy. They can influence decisions about what drugs are dispensed. These are major forces that influence rising drug costs today.

Hence, Caremark's patient education programs focus first on safety and effectiveness. Perhaps the biggest obstacle to the use of generic drugs is the perception that generic drugs are inferior. Patients need to know that they aren't sacrificing anything -quality of care or safety or effectiveness -- by using generic drugs. Only then will they be interested in the second message: generic drugs can save them money.

Caremark's Focus on Increased Generic Drug Utilization

Caremark promotes the use of generics through several different programs. These programs focus on three key audiences: patients, physicians and pharmacists.

- **Patient Programs -** Patients are encouraged to use generics through: (1) educational programs and (2) plan designs that create an economic incentive to use generics.

1. **Educational Programs**- These include general mailing that explain what generics are, and how patients can save money without compromising their care by choosing generics. They also include patient-specific mailings based on identifying retail brand name prescriptions dispensed when there was a generic drug available. In this case, Caremark will then a mailing to the patient in cases where the patient requested the prescription to be filled with a brand when a generic was available.
2. **Plan Design**- There are many ways to encourage generic drug utilization through plan design. Some of the ways to do this include:

   - ✓ Adjusting co-pay differentials to be higher for more expensive brand name drugs

   - ✓ Requiring patients to obtain explicit physician authorization in order to receive brand name dispensing when an approved generic product is available.

   - ✓ Requiring that patients accept generic products or pay the difference in price between the brand name and generic drugs, in addition to the standard co-payment.

   - ✓ Educational Mailings - Caremark will identify retail brand name prescriptions dispensed when there is a generic drug available, and will then send mailings to the

patient in cases where the patient requested the prescription to be filled with a brand when a generic was available.

Prescriber Programs - In addition to Caremark's programs to educate patients about generic drugs, Caremark also assists prescribers to choose generic drugs.

Caremark's physician education programs focus on promoting appropriate and cost-effective prescription utilization. Specific program activities include physician education via retrospective DUR (drug utilization review) letters, physician profiling and report cards, and face-to-face physician consultation through our national academic physician detailing program. These activities provide physicians with current clinical and economic information on pharmaceutical products and treatment protocols within specific therapeutic classes, including utilization of generic drugs. Some of these programs are described in greater detail below:

- Under Caremark's physician profiling program, a report is sent to physicians identifying claim-specific examples of brand products that could be converted to a generic drugs. Physicians will then be given patient-specific opportunities to prescribe a generic product. Twice a year, Caremark also produces a report showing the physicians' generic substitution rate (GSR) compared with peers in their specialty and against other physicians in the Caremark book of business. The report also shows the top five multisource brands where substitutions did not occur. Physicians may request a list of their patients who have been prescribed the multisource brand.

- Under the Caremark CustomCare Mail program DAW (Dispense as Written) prescriptions for brand name drugs are identified at Caremark's mail service pharmacy. A Caremark clinician contacts the prescribing physician to ask the physician to consider converting the prescription to a generic drug substitute and to educate the physician on the value of generic drugs. The final decision to dispense a brand name drug or generic substitute always rests with the prescribing physician. Caremark is successful in 45 percent of cases when requesting that physicians convert DAW prescriptions to a generic product.

- Caremark clinicians analyze and identify certain therapeutic categories that may include clinically similar drugs. Through a clinical pharmacist review, physicians are contacted and educated around the Caremark pharmacist's clinical recommendations. Caremark will then ask the physician to prescribe the generic alternative if clinically appropriate. This is done prior to filling at Caremark's mail service.

- Retail DAW mailings: Caremark will identify retail brand name prescriptions dispensed when there is a generic drug available, and will then send mailings to the physician who requested the prescription to be filled with the brand-name version of the prescription drug. Mailings educate the recipient on the safety, efficacy, and value of generic drugs, and on the actions they can take to have the next prescription filled as a generic drug.

- Generic Therapeutic Interchange at retail: Caremark clinicians identify certain therapeutic categories that may include clinically similar drugs. If a drug does not have a generic drug alternative, Caremark will send communications to the physician to consider prescribing a generic drug within the same class for the next prescription.

- Lastly, one of the most vital programs that will assist in the dispensing of generics by physicians is the use of electronic prescribing (e-prescribing). E-prescribing will allow for a better dialogue between physicians and their patients about the range of prescription options available by providing physicians with instant access to patient-specific formulary information, and the medication histories of their patients. This will allow physicians to discuss generic drug options at the point-of-prescribing rather than having these issues addressed only after the fact at the pharmacy counter or later. The requirement for Medicare drug benefit plans to implement an e-prescribing program will go a long way towards encouraging the widespread use of e-prescribing in the commercial market –by setting uniform federal standards that can be adopted by all participants in the health care system. This will, in turn, not only, encourage a better doctor-patient relationship, improve safety by reducing medication errors but also increase the utilization of generic drugs.

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Pharmacy Programs - Clinical pharmacy management programs alert pharmacists to opportunities to substitute generic drugs. These programs are employed both before and after a prescription is dispensed. Some of these programs are described below:

- Caremark's claim adjudication systems automatically identify when a brand name drug has a generic drug equivalent. The pharmacist will dispense the generic drug alternative, provided the physician has not written "Dispense as Written" (DAW). Retail pharmacies are given monetary incentives based, in significant part, on their efforts to improve our clients' generic drug substitution and dispensing rates. They improve performance in these areas by their own dispensing decisions and by influencing patients and physicians to use the most cost-effective, clinically appropriate medications. Individual pharmacists are not paid fees tied to performance results.

- The MAC (maximum allowable cost) program is an effective tool to promote utilization of generic drugs. The MAC program encourages generic drug substitution at the pharmacy level by establishing a ceiling price on the amount reimbursed to pharmacies for specific multisource brand-name and generic drug products. Pharmacy reimbursement is limited to the MAC price for drug products on the MAC list, and so pharmacies will retain more of the reimbursement if they dispense the less costly generic product. This creates a strong incentive for the pharmacy to dispense a generic drug.

Caremark helps pharmacies contain costs for patients and health plans by providing pharmacies with reporting tools for evaluating and improving their own performance and that identify missed opportunities. Pharmacies can access their own data electronically via downloadable spreadsheets in weekly e-mails and through other electronic media. This reporting enables pharmacies to drill down to the store level and view important cost-containment data, including generic drug substitution and generic drug dispensing rates, as well as comparisons with other pharmacies within each state.

Opportunities for Increased Use of Generic Drugs – Congress and the FDA

Caremark understands the value of generics and will continue to promote their appropriate use. Our historical efforts with beneficiaries, physicians and pharmacies and in support of health plan sponsors that we have described, as well as the efforts of others in the industry have paid off. Generic drug utilization has increased. In fact in 2003, across Caremark's entire client base, the overall generic substitution rate (GSR) was 94.8 percent. This means that about 95 percent of the time that a prescription was dispensed for a prescription drug with a generic equivalent available, a generic option was actually dispensed.

While generic substitution rates are over 90 percent, the generic dispensing rate, that is the percentage of total prescriptions dispensed that are generic, is only between 40-50 percent. Therefore, the greatest opportunity today to increase the savings realized from generic drugs lies not in increasing the rate of dispensing a generic drug when a generic drug is available, but instead, in increasing the availability of generic drugs generally. The more generic drug products that are available, the greater the overall rate at which pharmacies and PBMs like Caremark can dispense generic drugs. Increasing the availability of generic drug alternatives is the key to increasing overall generic drug utilization.

There are many factors that create barriers to the availability of generic drug alternatives. Some of these barriers can be addressed by Congress, and we urge the Congress to take action to reduce or eliminate these barriers so that lower cost generic drugs can be brought to market more quickly thereby, lowering overall health care costs to the American consumer.

The following sections outline three areas where Caremark believes Congress' actions can and will significantly affect generic drug utilization in the future:

1. First, the Medicare Modernization Act of 2003 made changes to the Hatch-Waxman Act to close perceived loopholes that allowed brand manufacturers to extend their patents beyond the time originally intended and deemed appropriate by Congress. We encourage Congress to continue these efforts in order to ensure that generic manufacturers have a level competitive playing field with brand name manufacturers.

2. Second, we urge Congress and the FDA to move forward on a regulatory process that leads to the approval of generic biologics as an alternative to brand name biologic products. This is truly the next frontier generic drug products and progress in this area should improve the affordability and accessibility of these very important, but expensive products.

3. Third, we ask that as Congress considers Bioshield II legislation that would enhance manufacturers' ability to bring bioterrorism countermeasures to market more quickly, it not unintentionally enact legislation that will inhibit the production of generic drug by. increasing the protections against market competition already enjoyed by brand manufacturers. This would serve as a major disincentives for generic drug manufacturers to make cost-saving generic products available to the American public.

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The Hatch-Waxman Act: Change in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. Title I of the Act sought to reduce the time it took for generic drugs to enter the market through the creation of an abbreviated new drug application (ANDA) process. For the first time, generic manufacturers did not need to repeat the preclinical and clinical research and trials that must be conducted by brand manufacturers before obtaining FDA approval. Generic pharmaceutical manufacturers instead needed only to show that their product was bioequivalent to the brand name product.

Caremark supports the intent of the 1984 Hatch-Waxman Act to encourage greater consumer access to lower-priced generic alternatives. However, over time, brand name manufacturers have found loopholes in the Act that allow them to extend their patents beyond the initial period, thereby frustrating the purpose of the law and delaying the introduction of generic drugs to market.

In 2003 Congress took an important step towards the promotion of generic drug competition with the changes to Hatch-Waxman enacted by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Under the new law, a brand name manufacturer no longer can receive 30-month stays for patents that are submitted to the FDA after an ANDA has been submitted for that product. In addition, the MMA included a modification to the start date of the 180-day exclusivity period that ensures that it is not used up in patent disputes.

We believe that the changes to Hatch-Waxman Act under the MMA are steps in the right direction. However, there is still work to be done in order to ensure that the Hatch-Waxman Act removes *all* barriers that exist to increased competition and generic drug availability.

Generic Biologics

When the provisions of the Hatch-Waxman Act were drafted, the biotechnology market was in its infancy. Since then, biotechnology and patent approvals for biotechnology products have grown rapidly. The growth in this market has recently caused policymakers and industry leaders to consider making generic alternatives to the brand versions of these biologic products available to consumers. This is particularly relevant now, given that 18 biologic products worth $10 billion a year will lose patent protection over the next few years.[4]

Biologic drugs tend to be very expensive, and in a time of rapidly growing prescription drug costs, it is important that biogeneric alternatives be considered to help create a more competitive, lower cost market. Similar to conventional drugs, when a generic version of a biological product becomes available, the market can be expected to be more competitive, and Caremark anticipates that it will be better able to negotiate discounts and offer those products at a lower cost to consumers and payers.

[4] Milne, Christopher-Paul and Catherine Cairns. "Generic Drug Regulation in the US Under the Hatch-Waxman Act". *Pharmaceutical Development Regulation 2003;* 1(1). Tufts Center for the Study of Drug Development, Tufts University.

Biotechnology and Specialty Pharmacy

Specialty pharmacy is a significant component to Caremark's overall service offering. Most of the specialty products that Caremark offers to consumers are biologic drugs. In contrast to conventional drugs, which are chemically synthesized from small molecules, many biologics are synthetic or recombinant versions of natural biologic substances such as proteins and enzymes that often require specific handling and storage techniques.

Caremark believes that the development of a streamlined FDA regulatory approval process for follow-on biologics would greatly increase generic product competition. We believe it is critical that the FDA use the administrative tools it has at its disposal to allow biogeneric alternatives to enter the market. In addition, we encourage Congress to create a legislative solution in areas where the FDA does not have administrative authority to do so, or is not using its current administrative authority due to concerns about legal interpretation.

Promote Regulatory Process to Approve Generic Biologics

To date, the FDA does not approve most therapeutic biologics through the new drug application (NDA) process, which is used to approve most drugs. There are however, several therapeutic biologics such as insulin and growth hormones that have, by exception, been approved via the NDA process.

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Biologics are generally approved separately, under the biologics license application (BLA) process, which is authorized under the Public Health Service Act (PHSA), not the Food, Drug and Cosmetics Act (FDCA) (which governs the NDA and ANDA processes). The BLA does not contain a process similar to the ANDA, which would expedite the approval of generic biologics. To date, the FDA has not made any administrative changes to either the BLA or the NDA/ANDA process to approve generic biologics.

Caremark encourages the FDA or Congress to move forward with an administrative process which would speed the availability of generic biologics to American consumers. We believe this could be done in one of two ways: 1) the FDA or Congress could create one approval process for biologics and pharmaceuticals, thereby allowing generic biologics to enter the market through the ANDA process; or 2) create an expedited approval process within the PHSA for generic biologic, similar to what was created under the Hatch-Waxman Act.

We understand that the FDA has publicly stated that the Agency has limited administrative authority to create a process whereby generic biologics may be approved. If the FDA continues to take this position, we encourage Congress to take action in order to address the issue.

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Bioequivalency

One of the most significant barriers to biogeneric approval is demonstrating the bioequivalence of these products. Progress is being made daily to better understand how to analyze and evaluate the clinical evidence that will prove bioequivalence. According to public comments from the FDA, significant progress is being made at the Agency to promote the development of bioequivalence evaluation tools, including molecular imaging techniques, in-vivo sampling methods, pharmacodynamic measures and mathematical models that test the performance of inhalation drugs.[5]

We believe that the science around bioequivalence testing has evolved to the point where the FDA should begin considering accelerated generic approvals of bioequivalent products. We believe the time is now ripe for the FDA and Congress to take action to ensure that this science and technology is harnessed to bring to market lower-cost biogeneric alternatives.

BioShield and the Impact on Generic Pharmaceuticals

BioShield I shows commitment to bio-preparedness

The enactment of BioShield I (P.L. 108-276) in July of 2004 was a defining moment in the nation's commitment to bio-preparedness. Clearly there is a need to develop new countermeasures for protection against the bioterror pathogens, toxins, or infectious diseases that potentially could be targeted against the United States.

[5] http://www.fda.gov/oc/speeches/2005/GPhA0301.html

Since the passage of BioShield I, some policy makers have raised concerns about the limitations of BioShield I, especially in dealing with the reluctance of pharmaceutical manufacturers to engage in research and development of biomedical countermeasures. Without public demand or appropriate incentives to spur countermeasures production today, the market for these products may not develop quickly enough.

Several bills have been introduced, that aim to strengthen BioShield I by giving the federal government tools to collaborate with private companies in developing countermeasures, thereby ensuring that the nation is more adequately prepared for potential bioterrorism attacks. One such bill, BioShield II (S. 975) would allow the Secretary of the Department of Health and Human Services (HHS) to deploy a variety of additional incentives, including the "wild-card" patent extension.

The wild-card patent provision

In general, under a "wild-card" patent provision, a brand name manufacturer may receive an incentive of additional market exclusivity on *any* drug, including non-countermeasure drugs and blockbuster drugs, for which it holds an unexpired patent. Specifically, as contained in S. 975, the Secretary of HHS would have the discretion to grant a manufacturer, who has won a BioShield contract, a wild-card patent extension ranging from six months to two years, for any

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qualified product the company manufactures upon successful development of a biomedical countermeasure. If you consider the just ten top selling brand names drugs that could be certified, the cost of this provision for the US buyers of prescription drugs, including consumers, especially seniors and the disabled and health plan sponsors, such as the federal government, exceed $45 billion.

Wild-card incentives delay generic drug competition

While Caremark supports some of the other incentives, such as tax incentives and liability protections, to encourage more pharmaceutical companies to participate in bioterrorism countermeasure, we strongly urge that Congress not pass legislation that includes protectionist patent-related incentives such as the "wild-card" provision. Such incentives will delay or even prevent generic drug competition for brand drugs, thereby undermining the balance so carefully achieved under Hatch-Waxman. By delaying the entry of generic drugs to the marketplace, these incentives would unnecessarily restrict access to less expensive versions of safe, effective and much needed medications, thereby burdening consumers, government, and private insurers with higher prescription drug bills.

While S.975 would require that the Secretary consider, among other things, the impact of the patent extension on consumers and healthcare providers in deciding whether to grant the wild-card extension, we are concerned that in some cases the urgent need for countermeasure

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development may seemingly outweigh the potential harm of extending the patent rights on a non-countermeasure drug. However, attempting to promote one public policy goal (security) by sacrificing another (access to affordable health care) through anti-competitive protectionist measures is not in the nation's interest, and not an appropriate tradeoff.

BioShield II patent incentives would propagate uncertainty in the generic drug marketplace

Under S. 975, all manufacturers who successfully produce the contracted countermeasure, including those that are awarded the wild-card extension, have the option to instead elect for full-term patent restoration on the countermeasure to compensate for time lost during the regulatory review process. In fact, at any time a contracting manufacturer granted the wild-card extension may choose the countermeasure patent restoration option instead of the wild-card, but the manufacturer may only choose one option. It could take five years or more for a successful countermeasure to be delivered, due to the time needed for research and development, during which time the patent on the selected wild-card drug may expire. The ability of a manufacturer to name a wild-card drug but never invoke the provision would significantly impact generic manufacturers, who would be deterred from developing a generic version of the selected wild-card drug due to the threat of litigation and liability for treble damages. As a result, American consumers, health insurers, and the prescription drug plans soon to be offering the new Medicare Prescription Drug benefit would have potentially fewer generic drug alternatives from which to choose, thereby increasing healthcare costs and eliminating treatment options for Americans.

BioShield II proposes to waive Hatch-Waxman limits on patent term restoration

S. 975 goes beyond the patent term restoration options under existing law, which allow only a fraction of the patent term lost during the approval process to be restored. It would allow the entire delay associated with regulatory review to be restored. This provision could allow the firm with a winning countermeasure drug to choose to extend the life of the patent on the new product to its full 17 years. Extending the life of brand name patents for this period of time is an unnecessary boon to brand manufacturers that will come at the price of the American consumer, as it will seriously inhibit generic drug manufacturers from bringing new generic products to market, thereby reducing the availability of lower cost generic products to consumers.

Congress should encourage the countermeasure and generic drug markets

The ability of the Federal Government to offer sufficient incentives to large pharmaceutical companies to invest substantial amounts of private capital towards the development of biomedical countermeasures – a relatively underdeveloped marketplace for research and development – is clearly important to the safety and security of our nation, but should not come at the expense of reduced generic drug options and therefore, reduced access to necessary health care.

Caremark continues to support the acceleration of research, development and manufacturing of novel biomedical countermeasure agents. Tax incentives and limitations on liability should be sufficient incentives for companies to invest in the production of biomedical countermeasures. Patent restoration and wild-card extensions are not in the best interest of the American people, generic pharmaceutical manufacturers, pharmacy benefit management companies, and the country's healthcare system at large.

Conclusion

Caremark is committed to delivering high quality health care services to American consumers. We provide, through our affiliates comprehensive drug benefit services to over 2,000 health plan sponsors and their plan participants throughout the U.S. One of the most important, clinically safe and effective, cost containment techniques that we employ as a PBM is the promotion of generic drug utilization through educational offerings, pharmacy programs and plan benefit design strategies. By encouraging generic drug utilization, we are able to offer safe and effective drugs at lower prices to consumers.

I thank the Committee members for asking me to speak about our business practices to promote appropriate utilization of generic drugs today, and look forward to an ongoing dialogue to determine how to increase the promotion and utilization of generic products in the future. I also appreciate the opportunity to raise legislative and administrative policy issues that could affect the ability to efficiently and expeditiously bring generic prescription drugs to market. Again, I

commend the Committee for considering this very important issue and look forward to further discussion and policy development in this critical area.

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